VI. CERTIFICATE OF NEED FOR MRI SERVICES

OVERVIEW

This section summarizes the Center's findings regarding certificate of need for MRI services. Separate portions are devoted to a discussion of the impact of CON on cost, quality, access and equity. The Center's conclusions regarding this body of evidence and reasoning about how to interpret it are provided at the end of the section.

IMPACT OF CON FOR MRI ON COSTS

Key Informant Survey

The key informant survey focused on CON for MRI contained several questions related to costs. A total of 13 interviews were completed; 2 declined to participate. The final sample included no representatives of government, 2 representing payers, 9 representing providers and 2 representing patients/consumers.

Impact on Number/Nature of MRI Units. The first question asked whether CON resulted in a perceptible difference in the number or nature of MRI units available in Michigan hospitals (those who believed it did have an impact were asked to describe the major effects of CON, whether positive or negative). All respondents agreed that CON limits the number of MRI units relative to the number that would exist if CON were not in place. Some characterized CON as being "very restrictive" but noted that standards had just changed in July (2002) so it remained to be seen what impact these would have.

There were mixed views on whether CON affects efficiency positively or negatively. According to one respondent, CON forces facilities to put their machines to maximum use, thereby contributing to efficiency. Yet other respondents implied that CON may be contributing to inefficiency in a variety of ways: a) by favoring hospital-based facilities, CON contributes to *inefficiency* since hospitals are not terribly efficient; b) most patients don't like to come for evening shifts, especially from 1:00-5:00 AM; while hospitals are configured to provide 24/7 access/staffing, this model does not work well for outpatient centers (hence even if hospitals were efficient, this may not be efficient for patients); and c) prior to the recent changes, the Henry Ford Health System was referring patients to Toledo due to an inability to expand.

Impact of Dropping CON on MRI Costs. A similar question was asked regarding whether dropping CON had any influence (positive or negative) on costs. The most common view was that CON removal would result in a proliferation of services, leading to excess use and excess costs. Some further believed that the surge in facilities was likely to eventually lead to the failure of some centers/programs.

Risks of Transition. Another question that evoked cost-related concerns related to the risks associated with immediate versus gradual lifting of CON. Three respondents saw no risks associated with immediate removal of CON. The rest anticipated a proliferation of facilities, resulting in eventual closure of some.

Literature Review: Impact of CON for MRI on Costs

No studies to date have specifically examined CON's impact on MRI costs. Instead, the limited available literature has focused on whether CON has inhibited the diffusion of MRI units. A study done for the state of Pennsylvania showed that CON had a negative effect on the supply of hospital-based MRI units; the same study found that stringent CON also had a negative effect, with both results being statistically significant (Lewin-VHI 1991). Another study confirmed that CON stringency has a strong negative impact on adoption of MRI: "for each one-point increase in CON stringency based on a 15-point scale, the odds of adoption among hospitals that had not yet acquired MRI decreased by 4.4 percent." (p=.09; Teplenskey et al., 1995: 456). That said, 3 other studies have examined the impact of stringent CON on hospital-based MRI units and found no significant effect.

Moreover, because all results are limited to hospital-based MRIs, they must be viewed with some caution. In the case of CT scanners, studies have examined CON's impact on hospital-based units but also on total units. The same study for Pennsylvania showed that CON (p<.05) and stringent CON (p<.01) significantly reduced hospital-based CT scanners (Lewin-VHI 1991). However, six other studies/analyses have shown that neither CON nor "mature CON" (i.e., programs in effect for some period of time) had significant effects on overall CT scanner supply, i.e., inclusive of both hospital-based and freestanding units. That said, one of these latter studies noted that by slowing diffusion in the short-run, CON in Massachusetts allowed hospitals to procure second generation scanners that were of better quality and lower cost (Lawthers-Higgins, Taft and Hodgman 1984).

Descriptive Evidence: States That Dropped Acute Care CON

MRI first began to be used clinically in 1982 (Baker and Wheeler 1998). Unfortunately, our data are limited to hospital-based MRIs for the period 1987-2000; for the 13 states that had already dropped CON by this year, we were unable to observe supply during the period CON was still in effect. Likewise, having only information about MRIs within hospitals is a serious limitation insofar as fixed magnets outside of hospitals account for 45 percent of the U.S. total (Baker and Wheeler 1998). Presumably, however, taking into account non-hospital-based MRI units, the relative growth in facilities in states lifting CON compared to those that retained

¹ The effect of CON was significant at the .05 level, meaning that if there really were no difference between states with CON and states without CON in terms of MRI units per million population, the likelihood of observing the study results was less than 5 percent. The effect of stringent CON was significant at the 1 percent level.

it would have been even greater. That is, it seems implausible that the rate of growth of MRI units outside of hospitals was faster in CON states than in states that lifted CON during this period.

Note also that we can only measure the availability of MRI *units* (measured in units per million and then indexed to the national average); we have no measure of actual MRI *use*. In our key informant interviews, it was clear that many MRI units in Michigan run 24 hours a day, whereas in states where supply is less constrained, this may not be true. Thus, a large apparent difference in availability of units in one state compared to another may not necessarily translate into an equivalent difference in actual use of MRI services. The following summarizes the findings from this analysis, which are reported in more detail in Appendix D. Our table provides figures for CT scanners, but we do not discuss these, as most of the patterns for MRI are repeated for this technology.

Trends in MRI Supply in States That Dropped CON. MRI supply in states that dropped CON before 10/1/86 rose from 108 percent of the U.S. average in 1988 to 136 percent by 1990, falling to 128 percent by 2000 (Table 6.1), suggesting a general pattern of surge followed by some retrenchment (an important caveat is that we do not know what their supply was prior to the year CON was dropped, which for some states occurred as early as 1983). This is exemplified by Idaho, which went from 98 percent of the national average in 1987 to a

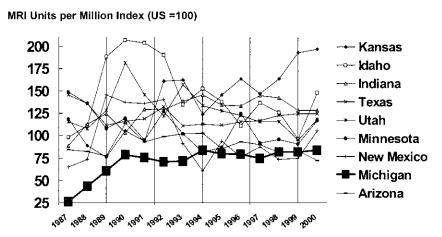
Table 6.1
Impact of CON Repeal on Growth in Hospital-Based Imaging Technology

	1980	1982	1984	1986	1988	1990	1992	1994	1996	1998	2000
	MRI Units Per Million Population Index (US = 100)										
CON in 2001											
Stringent	NA	NA	NA	NA	85.0	75.2	70.5	83.7	82.9	75.5	72.4
Moderate	NA	NA	NA	NA	101.9	83.0	81.3	91.3	89.7	109.6	110.4
Limited	NA	NA	NA	NA	115.4	110.5	102.0	113.6	121.2	124.8	113.2
Lifted CON											
Before 10/1/86	NA	NA	NA	NA	107.7	135.5	134.9	116.4	118.7	117.7	128.1
10/1/86-1989	NA	NA	NA	NA	96.4	129.7	142.4	147.3	148.4	161.1	172.8
1990 or later	NA	NA	NA	NA	125.0	124.1	113.0	118.7	145.7	149.2	137.8
Michigan	NA	NA	NA	NA	43.6	78.4	70.9	83.4	79.4	81.5	83.4
	CT Scanners Per Million Population Index (US = 100)										
CON in 2001											
Stringent	64.2	82.9	79.1	73.1	73.3	70.5	67.2	69.2	64.5	63.6	61.2
Moderate	75.5	78.1	84.9	93.4	101.8	105.8	107.7	116.1	114.7	121.1	122.5
Limited	107.7	105.7	108.4	113.7	111.5	112.9	113.0	115.0	118.9	125.0	116.1
Lifted CON											
Before 10/1/86	89.8	92.6	100.0	105.3	109.1	111.3	112.4	115.1	122.8	125.5	132.0
10/1/86-1989	108.5	103.0	105.9	117.0	130.9	142.7	148.6	155.7	161.6	165.6	175.7
1990 or later	126.0	120.6	163.2	156.1	131.0	130.1	137.6	145.3	164.0	148.0	156.0
Michigan	57.1	59.2	62.2	60.1	80.4	81.1	89.6	92.5	98.0	95.2	96.6

Source: AHA data reported in Tables E-3 and E-4.

peak of 207 percent by 1990, falling to 148 percent in 2000 (Fig. 6.1). Arizona, Indiana, New Mexico, and Utah displayed a similar pattern while Minnesota and Texas exhibited a pattern of starting above the national average in 1987 and gradually declining thereafter, with both states ending up above the national average in 2000; Kansas and Louisiana exhibited a series of peaks and troughs over this period because for the most part, growth in facilities expanded steadily, but in some years the growth was faster than the national average and in some years slower.

Fig. 6.1
MRI Trends in States Lifting CON Before October 1, 1986

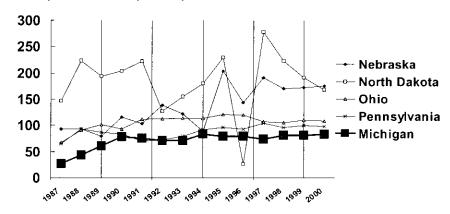


Source: AHA Hospital Statistics

Likewise, states that dropped CON in 1990 or later went from 119 percent in 1994 to 170 percent by 1997, falling to 138 percent in 2000. This is typified by North Dakota, which dropped CON in 1995; its MRI supply rose from 181 percent of the U.S. average in 1994 to a peak of 278 percent by 1997, falling to 169 percent today (Fig. 6.2). Nebraska and Pennsylvania had the same pattern. Interestingly, Ohio, which dropped CON for hospital-based MRIs in 1995, saw its supply go from 113 percent of the U.S. average in 1994 to a "peak" of only 121 percent by 1995, declining to 109 percent in 2000. However, this case illustrates the limitations of our data, since elsewhere it has been documented that diagnostic imaging centers (DICs) in Ohio grew more than 8-fold between January 1997 and December 31, 2000 (Ohio Department of Health 2000). Moreover, 67 percent of the growth in DICs occurred in 10 counties that lost hospitals following CON removal (Ohio Department of Health 2001), raising the same question (posed earlier regarding ASCs) of whether this growth contributed to their demise.

Fig. 6.2
MRI Trends in States Lifting CON in 1990 or Later

MRI Units per Million Index (US =100)

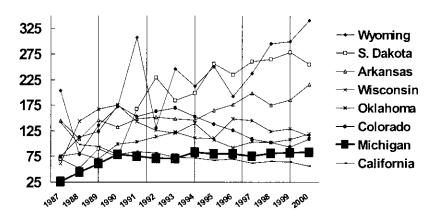


Source: AHA Hospital Statistics

A somewhat different pattern is seen in the middle wave of states that dropped CON (prior to 1990): MRI units in these states went from 96 percent of the national average in 1988 to 158 percent by 1991, falling somewhat thereafter and then eventually rising to 173 percent of the national average by 2000. This is exemplified by South Dakota, which went from 70 percent of the national average in 1987 to a peak of 229 percent by 1992, falling to 184 percent by 1993 and ending up at 255 percent by 2000 (Fig. 6.3). Arkansas and Wyoming exhibited a similar pattern, whereas Colorado and Wisconsin followed the more conventional "boom-bust" cycle noted earlier.

Fig. 6.3
MRI Trends in States Lifting CON
From October 1, 1986 – December 31, 1989

MRI Units per Million Index (US =100)



Source: AHA Hospital Statistics

What is noteworthy is that on average, the states dropping CON already were above the national average before CON was lifted; even so, their MRI supply typically rose even further above the U.S. average following CON removal. With the exception of the middle "wave" of states, an apparent "surge" in MRI facilities was followed by some retrenchment. It is worth noting, however, that the two states with arguably the highest degree of competition, California and Minnesota, displayed a very different pattern. Both dropped CON prior to 1987, so we do not have a "pre-CON" snapshot. But their relative MRI supply went from exceeding the national average by 40 percent in 1987 to below the national average by 1999. By 2000, California was 44 percent below the national average, while Minnesota's MRI has exhibited a recent "surge" ending up at 17 percent above the national average by 2000. How this picture might change were non-hospital-based MRIs included in our figures is unclear.

Trends in MRI Supply in States With CON. During this same period, the restrictiveness of Michigan CON evidently loosened over time, as the state's MRI supply went from 26 percent of the national average in 1987 to 83 percent by 2000. Similarly, states with stringent CON saw their MRI supply go from 55 percent of the national average to 72 percent during the same period. Thus, Michigan is "holding the line" to some extent, but not quite as much as in states with stringent CON. However, it is outperforming other states with moderate CON whose MRI supply rose from being nearly 25 percent below the national average in 1987 to being 10 percent above the average by 2000. During this same period, states with limited CON were relatively stable, having an MRI supply 16 percent above the national average in 1987 and 13 percent above by 2000. As shown in Fig. 6.1 throuh 6.3, Michigan generally has held down growth in MRIs somewhat better than states that dropped CON.

Conclusions. Lifting CON does not inevitably lead to "surge" in acquisition of new MRI units, but it is the most common pattern overall. Of the 19 states that dropped CON, 10 exhibited an MRI supply that was below the national average in 1987 (when our data begin) or in the year immediately prior to lifting of CON. While the subsequent surge in facilities in those states might be characterized as a "catch-up" phenomenon, all but 2 of these states ended up with a supply of MRIs in 2000 that exceeded the national average by as much as 140 percent. In most cases, the building "surge" is temporary and is reversed to some extent by market forces, but this reversal is rarely "complete:" only 4 states of the 19 ended up in year 2000 with a lower relative supply of MRI units than they had in 1987 (for states dropping before that year) or the year immediately prior to CON elimination. All in all, for the year 2000, the MRI supply in states that lifted CON is approximately double that observed in states with stringent CON. What this analysis cannot tell is whether the latter states permit "too little" or the former states have "too much" in the way of MRI services. However, it is worth noting that MRI availability appears to decline as HMO market share increases in a geographic area (Baker and Wheeler 1998); to the degree that market competition results in a better matching of patient needs/desires to actual supply, this would suggest that lower relative supply is not necessarily worse for patient welfare.

That said, it also is important to remember that there is not necessarily a one-to-one correlation between supply of MRIs and the cost to payers. Admittedly, if more machines are providing the same number of scans, health system costs will be higher (since the high fixed costs of MRIs will increase overall and be spread over the same number of patients, thereby raising unit costs). But limited supply also allows providers to charge more, so it is also conceivable that greater supply results in lower prices, i.e., reducing the profit earned per scan. Our analysis cannot demonstrate which of these possibilities occurs in the real world, but it is worth noting that the patterns of health spending do not move in lock-step with the patterns of MRI acquisition: for example, 13 of the 20 states that dropped or never had acute care CON had per capita health spending in 2000 that was *lower* than the national average, whereas spending for states with stringent CON was typically higher than the national average.

Multivariate Analysis

In our empirical analysis, we found that three years prior to dropping CON, states dropping CON experienced a significant drop (-22%) in their supply of MRI units (relative to the baseline period, but by the year immediately prior to dropping CON, their MRI supply was significantly above (+20%) the baseline). In the year CON was lifted, supply had already dropped to 24 percent below baseline and this persisted in the year immediately after lifting (19 percent below baseline). However, this effect apparently is temporary insofar as supply in post-lift years 4 and beyond is not significantly different from the baseline. In contrast, we found no significant results of lifting CON on supply of CT scanners in hospitals.

Consistent with other literature, our CON stringency results showed stringent CON programs (but not limited or moderate CON) were associated with a statistically significant reduction in hospital-based MRI units but no effect on the availability of hospital-based CT scanners (Table 7 in Appendix A).

IMPACT OF CON FOR MRI ON QUALITY Key Informant Survey

Five respondents thought that CON had no impact on quality of MRI services. Specifically, one respondent said that MRI quality in Michigan is very good, but this has nothing to do with CON. This was echoed by another who said that while there was some volume-quality relationship, no one, in the absence of CON, would operate a facility with a volume so low as to endanger quality. Three others concurred that CON had no impact on MRI quality.

The remainder believed CON improved quality either because of the volume-quality relationship (which several acknowledged was not as strong for MRI as for other services) or

because CON standards required services to meet certain standards (e.g., staffing etc.). With respect to volume-quality, one respondents was certain that CON improved quality for MRIs on grounds that high volume is associated with high quality; another noted that Michigan MRIs have the highest volume per unit in the country, so that if quality were associated with volume, then CON unquestionably would have an impact. Two others said they did not know specifically of scientific evidence of this volume-quality relationship for MRIs but presumed that greater experience must affect proficiency at the individual physician level; moreover, one further noted that given a shortage of skilled staff, any expansion in numbers of units would dilute quality by spreading these staff over more units.

Another acknowledged that the correlation between volume and quality was not as high for MRI as for other technologies regulated by CON, but nevertheless felt that there were measureable quality dimensions included in the Project Delivery Requirements under CON that helped ensure better quality (e.g., qualifications of MD who reads MRI results). A different respondent shared this view on grounds that Michigan had stringent requirements in terms of the qualifications of medical director, annual inspections etc. Another offered a similar view, but also pointed out that there was no policing of compliance with these requirements (even when facilities go back for a 2nd or 3rd MRI unit). Nevertheless, this individual felt that most facilities probably do comply, as did another who pointed to these same standards as evidence that quality was improved by CON, noting that most applicants took these seriously.

Relationship Between Hospital Volume and Health Outcomes

There are no real volume benchmarks for MRI that are analogous to those for cardiac surgery. The Leapfrog Group, for example, has set volume thresholds for CABG, coronary angioplasty, elective repair of abdominal aortic aneurysms, carotid endarterectomy and surgery for esophageal cancer, but none for MRI (Epstein 2002). Likewise, while the American College of Radiology includes some volume benchmarks for physicians (500 MRI exams performed or supervised and interpreted within the past 36 months), certification also can be obtained using other criteria (e.g., 3 months of documented training or 6 months documented experience). Moreover, there are no on-going annual volume requirements to maintain proficiency. Similarly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has no volume standards related to MRI.

IMPACT OF CON FOR MRI ON ACCESS

Key Informant Survey

Our survey included two questions related to access, the first focusing on whether CON affects access for uninsured and disadvantaged populations and the second related to geographic access for the entire population.

Impact on Access to MRI Services for Uninsured/Disadvantaged. Three respondents said CON had no impact on access to the uninsured and other disadvantaged patients. Four respondents thought CON resulted in worse access for these populations because it limits availability for the entire population and results in inconvenience for everyone. Ten respondents thought that CON improved access, but offered varying explanations for why: a) any facility receiving a CON is required to make services available regardless of ability to pay; b) limitations on MRI lowers health costs, so more people can afford coverage than they would otherwise; and c) by preventing cream-skimming, CON restrictions permit hospitals to cross-subsidize care for those who cannot fully pay for their own.

Impact on Geographic Access. Three respondents felt that the current standards resulted in a very uniform distribution of facilities across the state so that no particular areas were at a disadvantage. Four others thought that CON caused people in rural areas of the state to travel long distances to get to an MRI. One of these noted that in rural areas, mobile services are available, but the result is longer waiting periods for non-emergency studies since the mobile units are not always available; this individual acknowledged that rural hospitals generally would not have sufficient demand to run a profitable fixed unit, so an intermittently available mobile unit was preferable to an underutilized/unprofitable fixed unit. Likewise, another respondent suggested that while there inevitably were longer driving times in rural areas, the standards served to have a positive effect on MRI availability in such areas relative to what would occur otherwise. This was echoed by another respondent who said that under current standards, every hospital is permitted to have at least 1 fixed unit, so access in rural areas has been protected in this fashion. Another concurred that current standards create a level playing field since volume expectations have been handicapped to favor rural areas. One respondent said that CON had created an access problem in western Michigan, but another who identified the same problem noted that this should now disappear with the recent modifications in standards. Another said that lack of access in suburbs had gotten so bad that a group had said they would put in an MRI without a CON (thereby foregoing Medicaid and Medicare reimbursement).

Literature Review: CON for MRI and Access

We could locate no literature that specifically addressed whether CON for MRI (or any other imaging technology) had an impact on access.

IMPACT OF CON FOR MRI ON EQUITY

Key Informant Survey

Six respondents thought the current process was fair (although four of these noted that historically, CON had been tipped in favor of hospitals, but this was no longer true due to revisions in standards). Basically, so long as an applicant meets the numerical requirements, its application will get approved.

One respondent was agnostic, saying that by its nature, the process is inherently political and self-motivated, resulting in a system that is neither completely fair nor unfair. The CON requirements result in an open discussion with payers and other members of the community that has a temporizing effect on well-to-do communities. That said, power follows political contributions, so well-heeled communities have better odds than others. Nevertheless, even taking all that into account, the system is fairer than a complete free-for-all.

Of those who expressed doubts about the fairness of the current process, the reasons varied: a) one thought the process basically was fair but that unfairness arose by facilities that did not play by the rules (e.g., this individual has seen physician signatures that by all appearances are forged, but there is no enforcement/audit mechanism to preclude this, as whatever is submitted with an application is automatically accepted); b) another was disappointed to see that sometimes people serve on ad hoc committees even when they have an application under consideration; c) the current system favors teaching hospitals and other large institutions who have a voice in Lansing; d) notwithstanding changes in the standards, the system still favors hospitals over out-patient facilities since current rules do not allow outpatient facilities to rely on MRI unit-equivalents that are hospital-based; and e) the system basically is fair, but for political reasons, the process has been made longer and more cumbersome, giving the appearance of unfairness (a situation that could be remedied by proper staffing). The most negative view came from an individual who characterized the process as "arbitrary and highly politicized;" the process is slow and cumbersome and tied up by special interests. This individual thought that the Commission was not objective nor did it use objective criteria to make decisions that were in the best interests of the public.

Literature Review: CON for MRI and Equity

We could locate no literature that specifically addressed whether CON for MRI (or any other imaging technology) had an impact on equity, although the previous evidence cited in the acute care CON section relating to CON's impact on favoring certain types of facilities over others has some relevance.

CON FOR MRI: MEND IT OR END IT? Potential Improvements in CON for MRI

The key informants provided a number of suggestions regarding improvement, some of which have already been discussed in the acute care CON section. Of the remaining recommendations that relate exclusively to CON review of MRI, the ones cited by the most respondents or which appear to be the most important in terms of improving the process without diminishing its effectiveness are as follows:

- Improve the process of collecting physician signatures. The current process
 appears inordinately cumbersome on applicants and therefore prone to abuses.
 Allowing applicants to rely on electronic signatures might alleviate some of this
 burden while at the same time improving the integrity of what is submitted.
- Require ACR certification. Absent volume standards, one mechanism that might improve quality would be to require all facilities meet American College of Radiology certification requirements.

Elimination of CON for MRI

In our key informant interviews, most (77%) favored retaining CON for MRI services rather than eliminating it.

Impact of Dropping MRI CON. With one exception, all respondents thought the impact of dropping CON for MRIs would be negative, although their reasons differed. The most common view was that CON removal would result in a proliferation of services, leading to excess use, excess costs and lower quality (either because of the volume-quality relationship or because the limited supply of skilled staff (e.g., radiology techs) would be spread over too many units. Other observations included the following: a) Since Medicare will not pay more for scans, any higher unit costs resulting from the same volume being spread over more facilities were likely to be borne by private patients; b) misutilization is likely to be observed in for-profit facilities where investors are likely to exert pressure to make full use of expensive equipment; this excess utilization of MRIs would not be bad for patient health but clearly would have an undesirable impact on costs; c) while access in general might improve, it probably would not improve or could get worse for the uninsured; d) in the long run, the surge in facilities is likely to lead to eventual shut-down of some of them; e) the state currently has proficiency standards for X-ray and radiation therapy but nothing equivalent for MRI: having accreditation standards may help weed out unqualified providers; f) the shortage of radiation techs is nationwide, not unique to Michigan. It is hard enough to hire such individuals for hospital-based units. A proliferation of freestanding units is likely to draw techs away from hospitals since they can work 9:00-5:00 in outpatient facilities rather than 24-hour shifts in hospitals; and g) Blue Cross Blue Shield of Michigan (BCBSM) has their own Evidence of Necessity program (EON). Up until a year ago, EON had not approved any freestanding ambulatory surgical facilities, so the insurance commissioner was forced to make EON rely on CON. This respondent viewed this incident as evidence of collusion between BCBSM and hospitals, i.e., BCBSM is willing to assist hospitals in getting rid of their competition in exchange for favorable hospital payment rates that allow BCBSM to compete more effectively (for a long time, hospitals have had a most-favored-nation status with BCBSM, meaning that they are precluded from offering a competing health plan a lower price). This individual felt that without CON, there would be a danger of this kind of activity becoming more common, with nothing to prevent it.

One respondent thought that hospitals needed to figure out their role in the evolving health system; once a technology moves to outpatient, this individual saw no good reason for hospitals to compete with MDs to provide it. This person noted that BCBSM puts out several products, requires physicians to sign up for all and then ratchets down their fees whereas hospitals continue to get paid generously. One respondent thought that cherry-picking was a legitimate concern as more physicians opened specialty service clinics, but that such adverse effects could in theory be addressed through legislation; this individual thought that elimination of CON for MRIs would improve access and also enable hospitals to be more efficient since they could move units to locations where they were most needed. Another agreed that CON removal could improve efficiency to the extent that having too many units in hospitals was inefficient (e.g., too low capacity over weekends). Another thought that the short-term effects (as described above) would be negative but that the Indiana experience shows that some facilities will fail, which may be good.

CON vs. Market Forces. Three respondents thought that market forces were preferable to CON, with one of these conceding that removal of CON would have negative effects in the MRI market in the short run, but eventually have positive effects as market discipline took hold. Another of these thought that tighter licensing standards would be an adequate safeguard against quality being eroded by new entrants into the market. A fourth respondent thought a mix of CON and market forces was needed.

Nine respondents favored CON, with most noting that for one reason or another, markets do not work very well in health care. The chief concerns were that without CON, quality would be eroded and/or there would be more of a two-tiered system. One of these suggested that some sort of centralized planning process was essential in light of market failures in health care and that CON was preferable to the alternative that might arise were CON to be eliminated: the BCBSM EON program. Yet another noted that CON is better than a broken market, but also pointed out that if CON became a bureaucratic nightmare, this might no longer be true.

Immediate vs. Gradual Removal of CON. Three respondents thought that if CON for MRI services were to be removed, it should be immediate, although one of these indicated they were not completely sure and another felt that Michigan should wait to see the impact of the latest round of CON changes before taking further action.

Of these who thought a more gradual phase-out was preferable, the recommended phase-out periods ranged from 1-2 years to 50 years, with 5 years being the most commonly cited figure. There were several suggestions about how a phase-out could occur: a) first, exempt replacement units for review, then lift all restrictions; b) by gradually setting less stringent standards; c) looking to other states such as Ohio to see how they phased out their programs; and d) conducting a pilot test before lifting CON statewide. In addition, several

thought it was important that CON Commission monitor the phase-out to ensure it was proceeding in an orderly fashion. Others thought that without CON, it would be essential for Michigan to establish some sort of regulations regarding standards of care.

Risks Associated with Immediate Removal of CON. Three respondents saw no risks associated with immediate removal of CON: one of these thought that on the contrary, phasing out inevitably would lead to a ramping up of political debate over this issue.

Most others thought there would be a proliferation of services, culminating in lower quality and greater financial difficulties for hospitals as paying patients were diverted to for-profit outpatient facilities. Over-building of facilities would be likely to culminate in eventual closure of some and in the worst case, some hospitals might also close. Some also noted that staffing shortages would be aggravated. One of these thought that without BCBSM in the picture, it might be feasible to replacing CON with some sort of centralized process that permitted MRIs to compete head-to-head, which could have beneficial effects on quality only if consumers had information to judge quality reliably. Another felt that the cream-skimming issue has to be addressed. Part of the reason hospitals feel motivated to compete against outpatient facilities is that they see no alternative way of generating profits to cover their uncompensated care losses.

CONCLUSIONS

The Center concludes that the weight of the available evidence provides stronger support for continuing CON for MRI than for hospital beds. The empirical evidence regarding CON's impact on costs/availability of MRI services is mixed: individual cases suggest that lifting CON does often lead to a surge in acquisition of new facilities or equipment and some subsequent retrenchment as unsuccessful facilities fail. However, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of MRI units and found that if anything, controlling for all these factors, lifting CON was associated with a reduction of MRI units in the short run, but not in the long run. Our analysis further showed that stringent CON was related to a significant reduction in hospital-based MRI availability (consistent with other studies that have found states with stringent CON achieve significant reductions in the number of MRI units deployed). Our own analyses are limited in that we only have information for hospital-based MRI units for a limited time period; moreover, we do not have detailed information regarding which states actually regulate MRI services through CON. Thus, some states that "dropped CON" may never have been regulating MRI in the first place, in which case any subsequent trends in MRI supply cannot be attributed to CON's elimination. Regardless of the "general case," the key informant interviews provides fairly good evidence that Michigan's CON has inhibited growth in the supply of MRIs, but there are mixed views on whether this is good or bad for consumers.

With respect to *quality*, neither the key informant interviews nor literature suggest that CON for MRI adversely affects quality. However, there also is not solid volume-quality evidence or standards to warrant CON review. So if CON improves quality, it would have to be through the imposition of project delivery requirements cited in the standards, raising the question of whether the same result could be achieved through licensure rather than CON. In addition, one has to consider whether alternatives to CON (such as BCBSM's Evidence of Necessity Program) would achieve the same purpose.

Most of the key informants viewed CON as having a beneficial impact on access to MRI services for the uninsured and underinsured: we found no evidence to the contrary. On balance, CON appears to have improved access in rural areas relative to what would have been built and sustained in the absence of CON; conversely, however, access in suburban areas almost certainly is less than it would be in an unrestricted market.

Thus, whether to continue CON for MRI comes down to a trade-off: is it worth inconveniencing an uncertain number of residents living predominantly in suburbs in order to achieve relatively modest improvements (if any) in quality and similarly modest improvements in access?

If CON for MRI is retained, the following improvements should be considered: a) improve the process for collecting physician signatures to make it less cumbersome and less prone to abuse; and b) use professional certification standards to ensure high quality MRI services.

The following section reviews the Center's findings regarding CON for cardiac services.

VII. CERTIFICATE OF NEED FOR CARDIAC SERVICES

OVERVIEW

Michigan is one of 26 states to use CON to regulate cardiac catheterization laboratories (CCLs) and one of 27 states to regulate open heart units (OHUs) (AHPA, 2002). This section summarizes the Center's findings regarding certificate of need for cardiac catheterization and open heart services. For brevity, cardiac catheterization laboratories will be referred to throughout this section as CCL and open heart units as OHU. Cardiac catheterization is a diagnostic procedure, whereas therapeutic catheterization denotes percutaneous transluminal coronary angioplasty (PTCA). Separate portions are devoted to a discussion of the impact of CON on cost, quality, access and equity. The Center's conclusions regarding this body of evidence and reasoning about how to interpret it are provided at the end of the section.

IMPACT OF CON FOR CARDIAC SERVICES ON COSTS Key Informant Survey

The key informant survey focused on CON for OHU/CCL services contained several questions related to costs. A total of 9 interviews were completed; 4 declined to participate and 1 was unavailable. The final sample included no representatives of government, 2 representing payers, 7 representing providers and none representing patients/consumers.

Impact on Number/Nature of CCL/OHUs. The first question asked whether CON resulted in a perceptible difference in the the number or nature of CCL/OHUs available in Michigan hospitals (those who believed it did have an impact were asked to describe the major effects of CON, whether positive or negative). All respondents except one thought that CON had a clear impact in reducing the number of CCL/OHUs; the one exception thought CON had no impact on number/nature of CCLs.

There appeared to be some divergence of opinion over the extent of CON's impact, with a handful indicating the impact was relatively slight and the majority appearing to believe the impact was substantial (e.g., one characterized the bar as being set "very high" in Michigan). Similarly, most viewed these constraints positively, e.g., as contributing to greater quality, whereas others viewed them negatively, e.g., as stifling competition. Others expressed uncertainty about whether rules were constraining "good proliferation" or "bad proliferation."

Impact of Dropping CON on CCL/OHU Costs. A similar question was asked regarding whether dropping CON had any influence (positive or negative) on costs. A third of respondents thought there would be little or no impact on costs, with one suggesting that a temporary "surge" in building/costs would eventually be followed by a market shakeout that

ultimately would produce lower costs in the long run. However, the most common view (67%) was that CON removal would result in a proliferation of services, leading to excess use and excess costs.

Risks of Transition. Another question that evoked cost-related concerns related to the risks associated with immediate versus gradual lifting of CON. Four respondents (44%) saw no risks associated with immediate removal of CON. One third anticipated some proliferation of CCL/OHU facilities.

Literature Review: Impact of CON for Cardiac Services on Costs

As with MRI, no studies to date have specifically examined CON's impact on the costs of cardiac services. Instead, the limited available literature has focused on whether CON has inhibited the diffusion of CCLs/OHUs. An early study found that both young CON (p<.10) and mature CON (p<.05) significantly constrained supply of OHUs (Russell 1979). Likewise, a study done for Pennsylvania showed that CON had a negative effect on the supply of hospital-based OHUs (but no significant effect on CCLs); the same study found that stringent CON had a negative effect on both, with both results being statistically significant (Lewin-VHI 1991). In contrast, a previous analysis by the authors showed that neither young CON nor mature CON had a significant effect on OHUs, nor did lifting of CON (Conover and Sloan 1995). The same caveat noted for MRI applies to the CCL findings: had studies examined both hospital-based and freestanding CCLs, the results may have been different.

Several other studies are of relevance. One study that examined the economies of scale in open heart surgery found that most of the cost savings that result from spreading the fixed costs of OHUs over larger numbers of patients come from increasing the number of surgeries to 100 per year (McGregor and Pelletier 1978). Another study from the same time period concluded that the potential national savings that would result from consolidating OHUs into an optimal regional pattern would only be 2 percent of the annual cost of open heart hospitalizations (Schwartz and Joskow 1980). Based on data and assumptions from a single California hospital, another researcher concluded the potential savings would be ten times as large as this (Finkler 1979 and 1981). This later figure is similar to that found in a more recent study that examined the potential resource savings resulting from regionalization of OHUs within the VA health system (Menke and Wray 1999). Even taking into account the added costs associated with treating emergency cases at non-VA hospitals and transporting patients to regionalized facilities, this study concluded that the savings from closing an OHUs would amount to 18 percent of the overall costs of treating open heart surgery patients within a geographic area.

¹ The effect of CON on OHU supply was significant at the .01 level, meaning that if there really were no difference between states with CON and states without CON in terms of OHU units per million population, the likelihood of observing the study results was less than 1 percent. The effect of

However, a cautionary note is provided by a study of Level I trauma centers, showing that in states where such facilities are publicly designated (i.e., due to a statewide regionalized trauma system), charges per case were 165 percent higher than for Level II centers. In states where trauma centers self-designated themselves (implying some competition within geographic areas), this charge differential was only 16 percent (Goldfarb, Bazzoli and Coffey 1996). The authors were unable to determine whether this was because publicly administered systems were imposing added costs on these facilities or whether it was because the facilities were exploiting their market power to command higher charges. Hence this evidence could either be used to support regionalization of such facilities (on grounds they are very expensive) or to raise questions about whether the hypothetical efficiency benefits of regionalization will redound to the benefit of the general public.

Cardiac services have been described by hospital executives as "the centerpiece of most hospitals' strategies, a service with very high consumer visibility and demand, and a main driver of hospitals' profit margins" (see Wolfson, 2001: note 178). Such profits imply that market price for such services exceed the cost of providing it. In such a context, it is not clear whether any efficiencies resulting from regionalization would redound to the benefit of consumers or regionalized facilities that by definition are protected from competition. This complicates drawing strong conclusions about whether CON lowers cardiac care costs even if there were demonstrable evidence that it regionalized facilities into a more efficient configuration.

Descriptive Evidence: States That Dropped Acute Care CON

As with MRI, our data are restricted to hospital-based units, but our data run from 1980-2000, so we compare levels of supply before and after acute care CON was lifted in 19 states. Having only information about CCLs within hospitals is a serious limitation for the same reasons explained earlier for MRI. But as with MRI units, had we taken into account non-hospital-based CCLs, the relative growth in facilities in states lifting CON compared to those that retained it most likely would have been even greater. In contrast, OHUs are a more "pure" case insofar as there are no such units outside of hospitals.

As with MRIs, the American Hospital Association (AHA) data only allow us to measure the availability of CC/OH *units* (measured in units per million and then indexed to the national average); we have no measure of actual CC/OH *use*. However, Dartmouth Atlas data helps fill in this gap to some extent. Thus, a large apparent difference in availability of units in one state compared to another may not necessarily translate into an equivalent difference in actual use of CCL/OHUs. The following summarizes the findings from this analysis, which are reported in more detail in Appendix E.

Table 7.1
Impact of CON Repeal on Growth in Hospital-Based Cardiac Services

	1980	1982	1984	1986	1988	1990	1992	1994	1996	1998	2000
	Cardiac Catheterization Units Per Million Population Index (US = 100)										
CON in 2001											
Stringent	92.6	95.8	87.3	91.1	86.6	88.1	81.6	82.4	82.6	91.0	85.5
Moderate	86.2	82.4	81.7	77.8	80.5	87.7	93.0	91.4	89.3	92.4	94.7
Limited	106.0	105.2	105.0	109.7	104.0	107.5	103.5	106.6	114.3	117.4	111.0
Lifted CON											
Before 10/1/86	98.1	98.2	97.7	96.4	102.2	98.7	96.6	101.8	110.6	106.6	111.9
10/1/86-1989	109.2	121.2	118.8	121.3	118.4	109.3	101.6	117.8	111.2	111.2	120.5
1990 or later	109.1	128.2	131.9	139.2	133.3	130.9	125.3	127.3	138.4	111.2	115.5
Michigan	100.0	94.1	96.5	90.2	84.9	92.8	101.2	107.5	109.7	104.7	103.1
	Open Heart Units Per Million Population Index (US = 100)										
CON in 2001											
Stringent	54.7	65.5	54.1	52.1	44.3	49.9	45.4	53.0	50.8	52.0	52.7
Moderate	67.0	66.4	67.7	66.2	66.6	64.8	64.8	69.3	64.4	71.3	69.4
Limited	110.0	103.0	103.1	106.3	100.5	105.2	106.6	103.6	108.0	113.9	110.0
Lifted CON											
Before 10/1/86	106.9	108.5	110.5	117.1	125.1	123.1	124.0	124.0	127.8	122.0	118.9
10/1/86-1989	111.2	116.8	117.5	118.1	132.4	126.4	125.6	125.8	127.3	121.0	129.9
1990 or later	128.4	147.4	155.2	145.1	146.5	146.5	143.9	154.5	165.8	124.3	137.7
Michigan	75.8	83.1	84.3	80.1	79.2	80.4	80.2	86.5	84.2	86.7	87.1

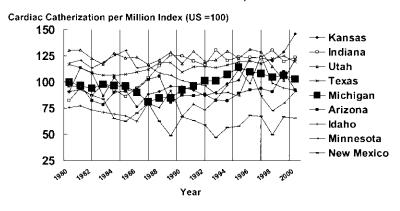
Source: AHA data reported in Tables E-5 and E-6.

Trends in Supply of Cardiac Services in States That Dropped CON. CCL supply in states that dropped CON before 10/1/86 rose from 98 percent of the U.S. average in 1980 to 102 percent by 1988, followed by 5 years of slight retrenchment, culminating in a supply in 2000 that was 112 percent of the national average (Table 7.1). This is exemplified by Arizona, which went from 90 percent of the national average in 1984 to a peak of 105 percent by 1988, falling to 81 percent in 1989 and rising to 93 percent in 2000. Idaho, Indiana, Kansas, and Texas displayed a similar pattern, but it is worth noting that any "surge" occurring in these states was modest in scope and delayed in time: that is, in Idaho and Kansas, relative CCL supply fell in the first three years following CON removal and only later "surged" followed by a retrenchment (Fig. 7.1). It is also worth noting that despite the increase in supply during this period, Arizona and Idaho had in 2000 a relative supply that still was below the national average; hence some of their growth in supply after CON was removed might be viewed as a "catch-up" phenomenon. In contrast, by year 2000, Indiana (124%), Kansas (146%) Texas (119%) and Utah (120%) all had supplies that exceeded the national average. In contrast, OHU supply in the states that lifted CON early was 7 percent above the national average in 1980 and grew fairly steadily to 19 percent above by 2000.

In sharp contrast to this general pattern, both Minnesota and New Mexico started with relative CCL supply below the national average before CON was dropped and by 2000 had

supplies that were more than a third lower than the U.S. overall. Other states in this group showed more variable patterns.

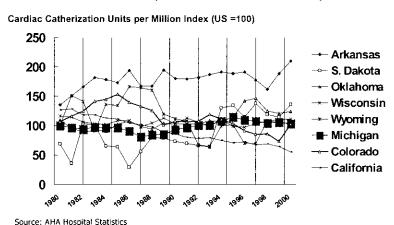
Fig. 7.1
Cardiac Catherization Trends in States Lifting CON
Before October 1, 1986



Source: AHA Hospital Statistics

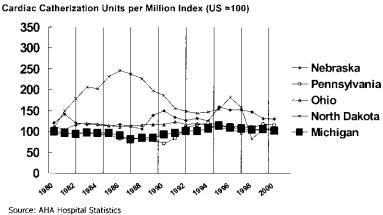
In contrast, in the middle wave states that dropped CON (prior to 1990) relative CCL supply fell from 121 percent of the national average in 1986 to a low of 102 percent by 1992, followed by a gradual rise to 120 percent by 2000. This is exemplified by Wyoming, which went from 180 percent of the national average in the year immediately prior to lifting CON (1986) to a low of 65 percent by 1993, and ending up at 104 percent by 2000 (Fig. 7.2). Colorado exhibited a similar pattern, whereas Arkansas and Wisconsin followed the more conventional "boom-bust" cycle noted earlier.

Fig. 7.2
Cardiac Catherization Trends in States Lifting CON
From October 1, 1986 – December 31, 1989



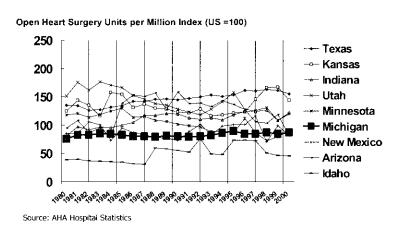
The last set of states to drop CON showed a different pattern, moving from 134 percent of the national average in 1995 to 115 percent by the year 2000. This is typified by Nebraska, which dropped CON in 1997; its CCL supply dropped from 152 percent of the U.S. average in 1996 to 130 percent by 2000. Pennsylvania had the same pattern (Fig. 7.3). Ohio and North Dakota exhibited a more conventional "boom-bust" cycle, but note that North Dakota experienced a far larger "boom" in the early 1980's before it dropped CON.

Fig. 7.3 Cardiac Catherization Trends in States Lifting CON in 1990 or Later



These general patterns are not terribly different for OHUs except that a) Michigan generally has been below most of the other states both before they dropped CON and through the year 2000; b) there are wider differences between the lowest and highest states. Among the states that dropped CON earliest, OHU supply has been guite stable over time with little evidence of an "explosion" in the number of facilities (Fig. 7.4).

Fig. 7.4 Open Heart Surgery Trends in States Lifting CON Before October 1, 1986



The same general pattern is observed in the middle group of states, with the notable exceptions of South Dakota and Arkansas (Fig. 7.5). These two states have seen a marked increase in OHU supply (although in the case of Arkansas this arguably began before CON was lifted). Likewise, in the last group of states to drop CON, supply also has been quite stable over two decades with the exception of North Dakota which saw a sharp decline in OHU supply following the lifting of CON (Fig. 7.6).

Fig. 7.5
Open Heart Surgery Trends in States Lifting CON
From October 1, 1986 – December 31, 1989

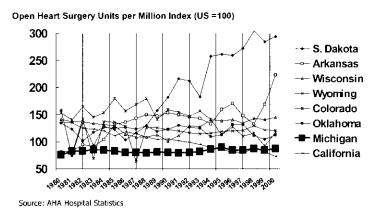
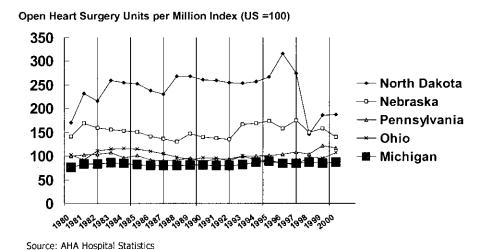


Fig. 7.6
Open Heart Surgery Trends in States Lifting CON in 1990 or Later



All in all, 12 of the 19 states dropping acute care CON already were above the national average for CCL supply before CON was lifted; of these, half saw their relative supply drop to below pre-lift levels by the year 2000. Similarly, for OHUs, 14 states were above the U.S. average before they lifted CON, of which 10 had relative OHU levels that were lower in 2000

than prior to lifting CON. Similarly, of the 7 remaining states (i.e., whose relative CCL supply was below national levels prior to eliminating CON), more than half continue to have a supply below in the national average in 2000; the same was true of 2 of the 5 states having an OHU supply below the national average prior to CON removal. As with MRI units, the two states with arguably the highest degree of competition, California and Minnesota, displayed a very different pattern: their CCL supply just before CON was lifted was roughly comparable to the national average and by 2000 had dropped, respectively, to 45 percent and 38 percent below the average. For OHUs, their achievement was even more impressive as both states started with a supply that was at least 18 percent above the national average prior to lifting CON and by year 2000 had obtained a one-third reduction in relative CON supply. This provides further evidence on the importance of competition in tempering the effects of CON removal.

Trends in Supply of Cardiac Services in States With CON. During this same period, Michigan's CCL was very stable, matching the national average in 1980, falling below this level for roughly a decade, seeing it rise to 10 percent above the average in 1996, but falling subsequently to 3 percent above the average by the year 2000. Similarly, for OHUs, Michigan has held supply to at least 10 percent below the national average throughout this 20-year period. States with stringent CON saw their CCL supply fall from 93 percent of the national average in 1980 to 86 percent by 2000; similarly, these states have consistently held OHU supply to at least 35 percent below the national average during this time. Thus, Michigan is not "holding the line" to quite the same extent as these more stringent states. However, it is doing better than other states with limited CON whose CCL supply has gone from being 6 percent above the U.S. average in 1980 to 11 percent above in 2000 and whose OHU supply has consistently (except for 1 year) exceeded the national average since 1980.

Conclusions. Lifting CON does not inevitably lead to "surge" in acquisition of new cardiac services, nor is it is the most common pattern overall for either CCLs or OHUs. Of the 19 states that dropped CON, 10 had a lower relative OHU supply in 2000 compared to the year prior to CON removal; the same was true of relative CCL supply in 8 states. In states where supply grew, the "boom-bust" phenomenon was less common than a smoother gradual rise in supply over time. That said, the states that lifted CON on average have higher relative supplies of both CCLs and OHUs compared to states with stringent, moderate or limited CON. However, there is a larger supply gap between stringent and limited CON states than there is between states with limited CON and states that lifted CON. This evidence is consistent with the idea that CON makes some difference and that stringent CON makes the most difference.

But the same caveats must apply to these observations as were noted for MRI CON: there also is not necessarily a one-to-one correlation between supply of cardiac services and the cost to payers. Cardiac services are well known for being large sources of hospital profits implying a wide gap between service costs and what is paid by payers. To the extent that

CON protects facilities from competition within a geographic area, this could merely increase costs to payers by permitting such facilities to obtain higher profits.

Descriptive Evidence: Dartmouth Atlas Data

Our earlier analysis of Dartmouth Atlas data (Table 4.9) showed that in 1999 (the latest year available) Michigan's coronary artery bybass graft (CABG) surgery rate exceeds the national average by 10 percent whereas the rate for all states without acute CON in 1999 was only 2 percent above the average. More specifically, the rate for states that lifted CON prior to October 1, 1986 is 5 percent below the national average (although the only one of these states that neighbors Michigan is Indiana, whose CABG rate is 11 percent above the national average). The rate for the "middle wave" of states that dropped CON is virtually identical to the national average (the only such state neighboring Michigan is Wisconsin, whose CABG rate is 2 percent below the national average). For states dropping CON after 1990, the rate is 17 percent above the average (Ohio and Pennsylvania are 2 of the 4 states in the latter category, with CABG rates 16% and 17% above the U.S. average respectively).

These figures are a reminder that constraining the supply of facilities or services is *not* necessarily equivalent to constraining resource use.

Multivariate Analysis

In our empirical analysis, we found no impact of dropping CON on open heart units, but some *reduction* in CCLs in post-lift years 1-3. However, this effect apparently was temporary as it did not persist in postlift years 4 and beyond. In contrast to some of the other literature, our CON stringency results showed no statistically significant effect of CON on either CCLs or OHUs (Table 7 in Appendix A).

IMPACT OF CON FOR CARDIAC SERVICES ON QUALITY Key Informant Survey

Two thirds of respondents thought CON had a positive impact on quality of CCL/OHU services, although one characterized the impact as minor and another noted that CON does not police units once they have gotten their CON to ensure that they actually meet the volume targets specified in their CON applications. Nearly all cited the relationship between high procedure volumes and higher quality as the reason CON contributes to better quality. However, one of these also noted that the technology is moving very rapidly, but Michigan's standards are not keeping pace. This individual acknowledged there will always be a lag in any bureaucratic system, but further noted that it took Michigan 2-1/2 years to recently change its open heart surgery services standards. MDCH is understaffed, but it has always been this way (e.g., going back to the 1980's). However, the situated was aggravated when Engler combined the department of mental health with the department of public health, and then has moved the department 5-6 times over the past 4 years.

One respondent was certain CON had no impact on quality while another was "not sure" and another indicated "probably not." The individual who was not sure noted that there was a debate over what number of procedures was associated with good quality, as there was some evidence of good outcomes even in low volume facilities.

Relationship Between Cardiac Services Volume and Health Outcomes

In contrast to MRI, there are good volume benchmarks for selected cardiac services. The Leapfrog Group, for example, has set volume thresholds for centers performing CABG (500 per year) and coronary angioplasty (400 per year) (Epstein 2002). There is solid empirical evidence of a volume-quality effect for CABG and cardiac catheterization (see Fig. 4.1). The most recent large-scale study to examine this showed that very high volume facilities achieved substantial (and statistically significant) surgical mortality reductions for CABG (-20%), aortic valve replacements (-24%), and mitral valve replacements (-23%) (Birkmeyer et al. 2002).

Moreover, there are two recent studies that have examined the impact of CON on CABG outcomes. The most recent of these is a national cross-sectional study that used Medicare data to determine surgical mortality for CABGs during 1994-1999 (Vaughan-Sarrazin et al. 2002). Risk-adjusted mortality was 22% higher in 18 states that had no CON regulation of OHUs during this period compared to 26 states that maintained such regulation during the entire period. Mean patient volume per center was 84% higher in states with CON regulation compared to those without, supporting the idea that CON led to improvements in outcomes by regionalizing facilties. While this study controlled extensively for various patient characteristics, it did not control for other factors such as managed care penetration, regional differences in the use of PTCA or various efforts by states to report CABG outcomes to consumers. Moreover, its cross-section nature limits the ability of the authors to draw cause-and-effect conclusions, as it is conceivable that states without CON regulation of OHS had worse surgical outcomes anyway for reasons unrelated to CON.

A different study compared CABG outcomes 3 years prior to Pennsylvania's elimination of CON to 3 years afterwards (Robinson et al. 2001). Despite a 25 percent increase in the number of open heart surgery programs once CON was lifted, the authors found no significant difference in the number of surgeries performed statewide nor any difference in mortality experience of hospitals that were approved under CON to perform CABG compared to those that developed open-heart programs following CON's removal. Thus, the advantage of this study is that it is a longitudinal comparison that focuses on the impact of lifting CON. The disadvantage is that it is a case study of a single state, and one that happened to also have a statewide public performance monitoring system that included hospital reporting of CABG outcomes. Absent this reporting system, it is conceivable that very different results might have been found.

Similarly, it has been reported that in Ohio, where CON has been lifted, 3 of 46 (6.5%) open heart facilities have volumes below American College of Cardiology/American Heart Association recommended minimums of 200-300 annual procedures per facility; however, further review of outcomes data for these low volume providers indicated "relatively few problems" (Ohio Department of Health 2001). What is not clear is whether problems would have been worse in the absence of Ohio's monitoring the situation or whether 6.5 percent is any worse than in Michigan, where volumes are monitored but not enforced post-approval of CON. An investigative report by the Phoenix Sun indicated that the rapid proliferation of OHUs in Arizona from 1985-1987 (CON was eliminated in 1984) resulted in a 35 percent increase in patient mortality rates from this procedure (Nathan 1998).

IMPACT OF CON FOR CARDIAC SERVICES ON ACCESS Key Informant Survey

Our survey included two questions related to access, the first focusing on whether CON affects access for uninsured and disadvantaged populations and the second related to geographic access for the entire population.

Impact on Access to Cardiac Services for Uninsured/Disadvantaged. Seven respondents said CON had no effect on access to the uninsured or disadvantaged populations. Two thought CON improved access, but for slightly different reasons. One thought that CON improved access in inner cities for reasons similar to those described in the general CON and hospital beds interviews. The other noted that most recipients of CON in Michigan are hospitals and since all hospitals in the state are not-for-profit, they are obliged to take all comers regardless of ability to pay.

Impact on Geographic Access. Two respondents said CON had no impact on geographic access since there was ample supply everywhere; one of these indicated that CCLs cannot be supported in any case without sufficient population, so population drives availability much more than CON. Another painted the same general picture in terms of suburbs vs. cities but was uncertain about CON's impact in rural areas.

Some viewed CON's impact on geographic access negatively, e.g., noting that most major heart hospitals were located in major cities, leaving rural areas with less access. Others noted that population growth had been in the suburbs, but CON rules have prevented facilities from following this growth, leaving suburbs at a relative disadvantage.

Others viewed CON's role more positively. For example, several observed that CON had made a tremendous effort to make CCLs more available in rural areas. Conceivably, rural areas might see better access to these technologies in the short-term without CON, but over the long term, many of these facilities inevitably would fail due to lack of sufficient demand for

services. In that sense, CON provided the stability and patient base to ensure survival of the facilities approved through the process. Another indicated that people in rural areas were resigned to having to travel longer distances to get medical care and other services. In this person's experience, people often drove past a local facility to go to a larger facility in a city; thus, even though CON does limit services to some extent, people are willing to go to where such services are available. Another respondent thought that while access in urban areas was not a problem, not enough thinking and evidence has been brought to bear on access problems for rural areas. For example, if transportation barriers are an issue for some rural residents, then current CON rules may be having a negative effect, but right now, most CON decisions are made only in terms of economic considerations rather than bringing other scientific evidence to bear to better understand the problem and what the right answer might be in terms of service availability.

Literature Review: CON for Cardiac Services and Access

We could locate no literature that specifically addressed whether CON for cardiac services had an impact on access.

IMPACT OF CON FOR CARDIAC SERVICES ON EQUITY Key Informant Survey

Two respondents thought that the current process was fair, although one qualified this response claiming not to be very knowledgeable about the politics of this issue. Both framed fairness in terms of whether facilities that met objectively set standards were given approvals. A third individual also said they were not qualified to judge. This individual used to be adamantly opposed to CON when it was a much more political process seeming to lack any objective standards and too often relying on outdated data that made it easy to reverse CON decisions in court. In contrast, the current system is a major improvement. In general, CON tends to restrict technology, but when it saw long waiting times for selected (unnamed) technologies, it re-adjusted the criteria, which this individual thought was an appropriate response. A fourth respondent was unable to comment.

Among those who viewed the current process as unfair, a variety of reasons were offered (some of which slightly contradicted one another): a) the current system is biased towards hospitals in general and teaching hospitals in particular to protect these institutions from cherry-picking that would leave them unable to cover their uncompensated care losses; b) the current system is biased towards hospitals over outpatient facilities in terms of CCL, but is neutral with respect to different types of hospitals. The system does not preclude outpatient facilities from qualifying for CON, but the system is stacked towards hospitals as only hospitals currently have CCLs right now; and c) the current system has become politicized, with special interest groups having gotten into the review process and/or those with "political pull" having more influence over the Commission.

Literature Review: CON for Cardiac Services and Equity

We could locate no literature that specifically addressed whether CON for cardiac services had an impact on quality, although the previous evidence cited in the acute care CON section relating to CON's impact on favoring certain types of facilities over others has some relevance.

CON FOR CARDIAC SERVICES: MEND IT OR END IT? Potential Improvements in CON for Cardiac Services

The key informants provided a number of suggestions regarding improvement, some of which have already been discussed in the acute care CON section. The following summarizes recommendations that relate exclusively to CON review of CCL/OHUs. Only one respondent thought that no improvements were needed.

- Modify Volume Requirements. One respondent thought that the current threshold of 300 OH procedures is not very realistic because today so many stents have replaced OH procedures. Thus, a facility performing 1200 stents and 250 OH procedures could have the same quality as a facility doing 300 OH operations. Current standards do not reflect that technology currently is headed in the direction of stents. Another individual thought that annual volume standards for facilities should be extended to individual physicians to ensure proficiency, i.e., 75 angioplasties and 100 CC procedures. Currently there appears to be no willingness by those involved in CON to do this.
- Increase Scientific Input into Standards-Setting. Several respondents expressed concerns that CON decisions were too dominated by considerations of what payers were willing to pay rather than on scientific evidence regarding what would be best for patient health. One respondent claimed that standards were too often set by payers wanting to limit the number of facilities, so the Commission "backed into" standards on this basis rather than basing them on latest scientific evidence. One respondent recommended tapping the Michigan Chapter of American College of Cardiac Care to obtain up-to-date standards of care to use in making CON decisions. Another respondent observed that the Committee on Cardiac Catheterization includes 6 experts, including cardiologists, nurses, administrators etc., but none of these was a cardiac surgeon.
- Establish Quality Monitoring System. One respondent felt that CON had no teeth in terms of quality control since it has no capacity to monitor whether facilities

² A specific example not related to CCL/OHU was the recent battle over PET scanners. This respondent thought the Economic Alliance had undue influence over the methodology, resulting in a number that was roughly half the level that would have been reached based on scientific evidence alone. Moreover, all 3 PET scanners that were approved are located in SE Michigan reflecting the bias

- comply with the standards needed to obtain a CON in the first place. If the Commission approves an application and the applicant fails to meet standards, it has no power to rectify this situation. A related concern is that being under MCDH makes CON more political: it might function better in a place where it has regulatory authority (including the staff to do its job).
- Permit Outpatient Facilities to do Therapeutic Cardiac Catheterization. One
 respondent said that Michigan's CON is antiquated in not permitting outpatient
 facilities to obtain CONs for therapeutic CC services (the current standards
 require facilities to be able to perform OH as back-up in an emergency). This
 results in all such units being in hospitals where costs are higher. Another echoed
 this sentiment, saying it also should apply to angioplasties (but further noting that
 Commission already is exploring this).

Elimination of CON for Cardiac Services

In our key informant interviews, most respondents (78 %) favored retaining CON for cardiac services rather than eliminating it.

Impact of Dropping CON for Cardiac Services. One respondent thought that dropping CON would have no adverse impact on costs, quality or access for cardiac services; if anything, it might improve access/quality since it will allow diffusion of CCLs beyond the 31 hospitals having OHUs. This person thought there would be no risk to quality since if a patient had a cardiac event, there would always be time to transfer to a different facility to do OH if that were needed. Another thought that there might be some adverse effects in the short run resulting from a surge in building both CCLs (especially outpatient) and OHUs. This would result in better access, but at a higher cost. In the long run, however, the market would take over, resulting in higher quality at a lower cost. As "losers" shut down, access would drop accordingly, but still would be higher than it would have been under CON; based on the experience in other states, Michigan would end up with more heart hospitals focused on delivering high quality services.

In sharp contrast, two thought that dropping CON would have negative effects on costs, quality and access with one indicating that the size of the impacts on cost and quality might be quite high. There would be higher costs since there are high fixed costs (implying that even if volume of procedures within the system remained the same, unit costs would go up). Apart from the volume-quality effect (which this respondent predicted would result in loss of life were programs begun in areas with insufficient volume), the limited supply of trained staff will mean that new programs may rob existing programs of their staff. Another respondent also thought the impact would be "catastrophic" as freestanding heart hospitals and physician-owned facilities steered patients away from existing hospitals, thereby hurting financial viability of the latter. With respect to access, however, the uninsured and other

disadvantaged populations would have worse access due to lower cross-subsidies for care, but those with insurance probably would find access improved. Another respondent said that access was not the issue: hence, there would not be much difference with or without CON, but removing CON would negatively affect costs, and one could make a "weak argument" regarding a negative effect on quality. This individual pointed out that this year, for the first time, Michigan has established physician-level minimum quality requirements (75 PCI or 100 diagnostic); physicians who fall below these thresholds will be sent an advisory letter, but the CON Commission has no authority to do anything beyond this.

Another respondent thought that only 1 or 2 more programs might emerge were CON to be eliminated; hence the negative effects on costs and quality were likely to be small. Another was uncertain, but also thought the CON removal would only result in a few more OH programs; furthermore, this individual did not expect this would increase the overall volume of procedures. Instead, the current number would simply be spread across more programs. This person was less certain about the impact on CCLs. Another respondent painted a parallel picture for CC services, indicating that some marginal hospitals would enter this business without CON, resulting in higher costs and lower quality as they pulled business from existing labs.

CON vs. Market Forces. Two thirds of respondents unequivocally thought CON was preferable to market forces. One of these cited an Advisory Board report on what happened in Ohio following CON removal, characterizing the resultant proliferation of facilities as "irrational exuberance." This individual also pointed out that managed care had not really taken off in northern Michigan, dimming the prospects for economic discipline. The Leapfrog Group had suggested some useful changes that might make the prospects for market forces more promising, but the issue is how to pay for these improvements in patient information related to quality. Moreover, Medicaid historically always has been a poor payer for hospitals and now Medicare (especially the 1997 Balanced Budget Act) has put a lot of hospitals in difficult financial circumstances, forcing them to lay of employees etc. In this context, it would be unwise to aggravate their situation by getting rid of CON (leaving them with even less ability to cover their uncompensated care costs). Another of these CON proponents indicated that market forces would be preferable if they worked, but that until patients can better distinguish good quality hospitals/physicians from those with poor quality, CON is the most reliable means to ensure quality. An additional respondent indicated some uncertainty and would need to examine the evidence more carefully, but guessed that CON was slightly preferable.

One respondent thought unequivocally that the market was better, while another felt that in the long run, having no CON would be better for patient access; however, the resultant competition also would affect the finances of some facilities so the state would have to find a way to deal with the uncompensated care issue.

Immediate vs. Gradual Removal of CON. Two thirds of respondents thought that if CON were to be removed, it should be immediate. One of these thought that dragging it out would simply reward those who were most aggressive, resulting in inequities. Another noted that without state involvement, private payers probably would be more inclined to use national guidelines and other tools to keep utilization/costs from getting out of control.

One third thought that phasing out CON was preferable, with two suggesting a 5 year period in which to accomplish this. One thought this would allow the system to adjust to the arrival of more for-profit players. Another recommendation a phaseout in conjunction with effective comprehensive health planning and rigorous public reporting on quality. Consumers could drive the market if they were educated regarding the volume-quality relationship and given information on volumes for each facility (historically, hospitals have resisted reporting on quality, which this individual thought made them part of the problem). Likewise, the public needs to know how much different facilities charge for the same service.

Risks Associated with Immediate Removal of CON. Three respondents thought there would be no risks associated with immediate lifting of CON. One of these thought that once CON were dropped, several cardiology groups would immediately build a physician-owned and operated heart hospital, but did not view this as a problem or risk. A fourth thought there would be no immediate risk to the general population, but that with new players coming in, the current providers would have to get better or they would lose market share.

Another thought there would be no risks except in the area of long term care (which was not a focus of this analysis) and MRIs, with too much capital investment in building too many MRIs that would be sold as screening tests. One respondent thought the chief risk of immediate CON removal would be the irrational proliferation of services based on erroneous beliefs about profitability rather than quality, need or cost-effectiveness. Another thought that the financial losses resulting from cherry-picking would pose the greatest risk. Similarly, another thought that greatest risk was the proliferation of for-profit CLL/OHUs programs not affiliated with hospitals. The last respondent focused on the risk to quality, noting that without CON, no one would have to fill out the Annual Hospital Statistical report that requires facilities to provide a break-down of the volume of all CON-related services/procedures (by physician and type of procedure). So there would be less information and accountability for quality.

Alternatives to CON Regulation

The Maryland Health Care Commission recently completed a comprehensive review of CON regulation of cardiovascular services, examining in the process, the approaches taken by other states. The following information is summarized from a much more detailed analysis contained in the Commission's report (MHCC 2001):

 Massachusetts dropped CON approval of CCLs in 1997, substituting licensure requirements for such facilities. A multidisciplinary committee advising the Department of Public Health has the authority to recommend that CCLs performing within a certain volume range continue to be licensed or delicensed. The committee may also recommend that a hospital may allow physicians performing within a certain range of volume to continue performing CC procedures. The state collects administrative on both CCLs and OHUs to measure compliance.

- Nevada also uses licensure rather than CON to regulate both CCLs and OHUs, with annual review and inspection. Licensed OHUs must maintain OH registries (which are reviewed on inspection, as there is no requirement that hospitals submit these to a central database). The state may deny, suspend, or revoke the license of hospitals not meeting minimum volume or adjusted mortality rate standards.
- New York uses CON to regulate CCLs and OHUs, relying on risk-adjusted mortality rates in their review of CON applications; these data also are published annually by hospital and by surgeon.
- Ohio deregulated CCLs and OHUs on March 1, 1998, placing a temporary moratorium on adult low-risk CCLs (which was lifted once new regulations were issued in January 2000). Ohio does not have hospital licensure, but reviews individual services for quality of care; hospitals must submit aggregate data on outcomes to the state (which also are publicly available). Volume goals cannot be used as the sole indicator of performance, but may be used in conjunction with outcomes data; failure to meet volume targets for 2 consecutive years triggers an extended review of cardiac services. The Department may impose fines or shut down services for noncompliance.
- Pennsylvania adopted licensure rules for CCLs and OHUs following CON elimination in late 1996. Hospitals providing cardiac services are required to report data on mortality, morbidity, infections, complications, patient risk factors and volume of procedures performed. If a review leads to quality concerns, the Department reviews the program. The Department has begun to use outcomes data from the Pennsylvania Health Care Cost Containment Council (PHC4) to make licensure decisions. PHC4 is an independent agency whose mission is to address health costs; the Council publishes risk-adjusted mortality rates for CABG by hospital and surgeon as part of its efforts to better inform consumers. Reportedly, significant resources are involved in this data collection effort.
- In addition to CON review of cardiac services, Rhode Island has adopted standards for CABG and coronary angioplasty programs (the Department of Health has statutory authority to adopt licensing standards for specific tertiary services where peer-reviewed literature demonstrates a significant relationship between volume and quality). These regulations include minimum standards for volume and survival rates and hospitals with approved programs must submit aggregate data to the Department (a former cardiac services registry provided very expensive). These data are publicly available and the Department may revoke or suspend any program not in compliance.

 Arizona dropped CON in March 1985, but makes available to the public information about each hospital on its number of discharges, average length of stay and average charge by DRG.

CONCLUSIONS

The Center concludes that the weight of the available evidence provides stronger support for continuing CON for cardiac services than for hospital beds. The empirical evidence regarding CON's impact on costs/availability of cardiac services is mixed: individual cases suggest that lifting CON does typically lead to a surge in acquisition of new facilities or equipment (although some states have experienced this). Moreover, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of CCLs/OHUs and found that if anything, controlling for all these factors, lifting CON was associated with a reduction of CCLs in the short run, but not in the long run. Our analysis further showed that stringent CON had no significant effects (although other studies have found that states with stringent CON achieve significant reductions in the number of CCLs/OHUs deployed). Our own analyses are limited in that we only have information for hospital-based CCLs; moreover, we do not have detailed information regarding which states actually regulate MRI services through CON. Thus, some states that "dropped CON" may never have been regulating cardiac services in the first place, in which case any subsequent trends in CCL/OHU supply cannot be attributed to CON's elimination. Regardless of the "general case," the key informant interviews provides fairly good evidence that Michigan's CON has inhibited growth in the supply of CCL/OHUs, but there are mixed views on whether this is good or bad for consumers.

These subjective beliefs are only partially borne out by reality: Michigan's OHU supply is 13 percent below the national average, but its CCL supply is 3 percent above. Moreover, the Dartmouth Atlas data show that notwithstanding its holding supply of OHUs so far below the national average, its CABG rate for Medicare patients is 10 percent higher than the U.S. average, suggesting the possibility of some "excess care" (or more positively, as an indication that CON has not constrained supply of OHUs "too much"). But the same is true of Indiana, Ohio and Pennsylvania even though they have dropped CON suggesting CON may not have much impact overall on quantity of services provided even if it might constrain supply of facilities.

With respect to *quality*, both the key informant interviews and literature suggest that there a solid volume-quality relationship for both CCs and OH surgeries, with mortality rates for the latter being reduced by 20 percent or more in high-volume facilities. However, the literature on CON as it relates to CABG is mixed: one study found that states with CON had better surgical outcomes, whereas a case study in Pennsylvania found no evidence that lifting CON resulted in worse outcomes even though the supply of OHUs increased by 25 percent after CON was removed.

Most of the key informants viewed CON as having no impact on access to cardiac services for the uninsured and underinsured. Conversely, CON appears to have improved access in rural areas in the opinion of most respondents and the impact on access in suburbs did not appear as severe as was described for MRI units.

Thus, whether to continue CON for cardiac services seems less of a trade-off than for MRIs: the supply of services seems distributed well enough that there are not the same concerns about access in suburbs. There's more evidence than in the case of MRIs that CON may improve quality because of the volume-quality effect and the evidence that CON improves access in rural areas is probably at least as good for cardiac services as it is for MRIs. If CON for cardiac services is continued, it seems reasonable to adopt a recommendation of the Maryland Health Care Commission in its recent comprehensive review of CON: "The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission." (MHCC 2001).

The following section provides the report's final conclusions.

VIII. CONCLUSIONS

The Center recognizes the sweeping changes that continue to occur both in the evolution of medical technology as well as in health care delivery and financing. The consultants believe that the stronger market forces being ushered in by these changes offer considerable potential for curbing costs. With its roots in the rapidly disappearing cost-based, third party reimbursement mechanisms of the past, CON is becoming clearly less relevant as a cost containment mechanism. Primary justification for CON, therefore, must rest on its ability to improve or maintain quality and/or access to care.

FINDINGS REGARDING GENERAL CON

Upon reviewing a large body of national and Michigan-specific material regarding acute care CON, including an analysis of what happened in states that dropped acute care CON, the Center found that:

- There is little evidence that CON results in a reduction in costs and some evidence to suggest the opposite;
- Removal of CON does not consistently lead to a "surge" in either acquisition of new facilties or medical expenditures;
- Because it is reasonably well-established that higher volume facilities generally achieve better health outcomes (e.g., lower mortality rates), the higher volumes that accompany specialization of facilities should improve health outcomes. While the general evidence that CON actually achieves such specialization is relatively weak, we did find evidence in Michigan that CON does constrain supply of MRI units, open heart programs and cardiac catheterization facilities;
- It is an open question whether any quality improvements achieved through CON might
 be as effectively or more efficiently be achieved using an alternative mechanism such
 as hospital outcomes reporting or quality standards enforced through a licensure
 process;
- CON may have a beneficial impact on access to care for the uninsured and underinsured, but the evidence is thin and even if true, such an impact is relatively modest in the context of the state's 1 million uninsured;
- CON appears to improve inner city access at the expense of access in suburban areas, hence elimination of CON could create financial difficulties absent some sort of alternative mechanism, such as a hospital pool, that would more equitably distribute the burden of uncompensated care.

All in all, justification for the current CON system in Michigan entails a trade-off in which the state must balance the costs of retaining CON (both in terms of the state's budget as well as the hidden costs imposed by the process on the health system) and lower access for a growing population living in suburban areas against modest potential gains in quality and/or access that conceivably be attained by other means. How much weight to attach to these effects ultimately is a political calculation well beyond the scope or purpose of this report. But in light of the state's fiscal crisis, a useful thought experiment might be to consider whether anyone would propose adopting CON in 2003 if the system were not already in place. In light of the evidence presented, reasonable people are likely to disagree on the answer to this question.

An examination of potential alternatives to CON, such as quality reporting mechanisms or hospital pooling mechanisms, were beyond the scope of this report. These would require further analysis if it were determined that elimination of selected components of CON were warranted. Conversely, if it is decided that acute care CON should be retained, some improvements suggested by Michigan key informants include:

- more staffing;
- enforcement of standards;
- improve/streamline the standard-setting process so that it is less cumbersome.

FINDINGS REGARDING CON FOR HOSPITAL BEDS

Upon reviewing an extensive body of material regarding CON for hospital beds, the Center found that:

- The weight of the available evidence provides weak support for continuing CON for hospital beds. The empirical evidence regarding CON's impact on costs/availability of hospital beds provides little reason to believe that lifting restrictions on beds would result in a surge in building of new facilities;
- With respect to *quality*, neither the key informant interviews nor literature suggest that CON for beds per se affects quality. To the degree there are concerns about volume and quality, these could be addressed by continuing CON regulation of selected facilities (e.g., open heart units) rather than hospital facilities in general;
- The strongest case for continuing CON for hospital beds relates to access. As noted
 earlier, it is an open question whether removal of CON would produce the two-tiered
 system many fear, with hospitals fleeing the inner cities to relocate in the suburbs
 jeopardizing access to care for selected populations and/or financial health of
 hospitals that remain.

Thus, whether to continue CON for hospital beds also comes down to a trade-off: is it worth inconveniencing an uncertain number of residents living predominantly in suburbs in order to achieve relatively modest improvements (if any) in access? If CON for beds is continued, the following improvements were suggested for consideration by key informants: a) fix bed need methodology so that it is based on more current data; b) increase flexibility by permitting transfers of beds within hospital systems; and c) develop a mechanism to take excess capacity offline.

FINDINGS REGARDING CON FOR MRI

Upon reviewing a smaller and less complete body of material regarding CON for MRI services, the Center found that the weight of the available evidence provides stronger support for continuing CON for MRI services than for hospital beds.

- The empirical evidence regarding CON's impact on costs/availability of MRI services is mixed: individual cases suggest that lifting CON does often lead to a surge in acquisition of new facilities or equipment and some subsequent retrenchment as unsuccessful facilities fail. However, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of MRI units and found that if anything, controlling for all these factors, lifting CON was associated with a reduction of MRI units in the short run, but not in the long run.
- Our analysis further showed that stringent CON was associated with a statistically significant reduction in MRI availability, consistent with the findings from other studies. Our own analyses are limited in that we only have information for hospital-based MRI units for a limited time period; moreover, we do not have detailed information regarding which states actually regulate MRI services through CON. Thus, some states that "dropped CON" may never have been regulating MRI in the first place, in which case any subsequent trends in MRI supply cannot be attributed to CON's elimination.
- Likewise, the key informant interviews provide fairly good evidence that Michigan's CON has inhibited growth in the supply of MRIs, but there are mixed views on whether this is good or bad for consumers.
- With respect to quality, neither the key informant interviews nor literature suggest that CON for MRI adversely affects quality. However, there also is not solid volume-quality evidence or standards to warrant CON review. So if CON improves quality, it would have to be through the imposition of project delivery standards, raising the question of whether the same result could be achieved through licensure rather than CON. In addition, one has to consider whether alternatives to CON (such as BCBSM's Evidence of Necessity Program) would achieve the same purpose.

- Most key informants viewed CON as having a beneficial impact on access to MRI services for the uninsured and underinsured: we found no evidence to the contrary.
- On balance, CON appears to have improved access in rural areas relative to what would have been built and sustained in the absence of CON; conversely, however, access in suburban areas almost certainly is less than it would be in an unrestricted market.

Thus, whether to continue CON for MRI comes down to the a somewhat different trade-off than that posed by CON for hospital beds: is it worth inconveniencing an uncertain number of residents living predominantly in suburbs in order to achieve a reduction in MRI supply (which may or may not translate into parallel reductions in utilization or costs) or relatively modest improvements (if any) in quality and similarly modest improvements in access?

If CON for MRI is retained, key informants suggested the following improvements: a) improve the process for collecting physician signatures to make it less cumbersome and less prone to abuse; and b) use professional certification standards to ensure high quality MRI services.

FINDINGS REGARDING CON FOR CARDIAC SERVICES

Upon reviewing a smaller and less complete body of material regarding CON for cardiac services, the Center found that the weight of the available evidence provides stronger support for continuing CON for cardiac services than for hospital beds.

- The empirical evidence regarding CON's impact on costs/availability of cardiac services is mixed: individual cases suggest that lifting CON does typically lead to a surge in acquisition of new facilities or equipment (although some states have experienced this). Moreover, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of open heart/cardiac catheterization (OH/CC) services and found that if anything, controlling for all these factors, lifting CON was associated with a reduction of CC services in the short run, but not in the long run.
- Our analysis further showed that stringent CON had no significant effects (although
 other studies have found that states with stringent CON achieve significant reductions
 in the number of OH/CC services deployed). Our own analyses are limited in that we
 only have information for hospital-based CC services; moreover, we do not have
 detailed information regarding which states actually regulate cardiac services through
 CON. Thus, some states that "dropped CON" may never have been regulating

cardiac services in the first place, in which case any subsequent trends in OH/CC services supply cannot be attributed to CON's elimination.

- Regardless of the "general case," the key informant interviews provides fairly good evidence that Michigan's CON has inhibited growth in the supply of OH/CC services, but there are mixed views on whether this is good or bad for consumers.
- These subjective beliefs are only partially borne out by reality: Michigan's OH services supply is 13 percent below the national average, but its CC services supply is 3 percent above. Moreover, the Dartmouth Atlas data show that notwithstanding its holding supply of OH services so far below the national average, its CABG rate for Medicare patients is 10 percent higher than the U.S. average, suggesting the possibility of some "excess care" (or more positively, as an indication that CON has not constrained supply of OH services "too much"). But the same is true of Indiana, Ohio and Pennsylvania even though they have dropped CON suggesting CON may not have much impact overall on quantity of services provided even if it might constrain supply of facilities.
- With respect to quality, both the key informant interviews and literature suggest that there is a solid volume-quality relationship for both CCs and OH surgeries, with mortality rates for the latter being reduced by 20 percent or more in high-volume facilities. However, the literature on CON as it relates to CABG is mixed: one study found that states with CON had better surgical outcomes, whereas a case study in Pennsylvania found no evidence that lifting CON resulted in worse outcomes even though the supply of OHUs increased by 25 percent after CON was removed.
- Most key informants viewed CON as having no impact on access to cardiac services
 for the uninsured and underinsured. Conversely, CON appears to have improved
 access in rural areas in the opinion of most respondents and the impact on access in
 suburbs did not appear as severe as was described for MRI units.

Thus, whether to continue CON for cardiac services seems less of a trade-off than for MRIs: the supply of services seems distributed well enough that there are not the same concerns about access in suburbs. There's more evidence than in the case of MRIs that CON may improve quality because of the volume-quality effect and the evidence that CON improves access in rural areas is probably at least as good for cardiac services as it is for MRIs. If CON for cardiac services is continued, key informants recommend enforcement of quality standards. Potentially, this could be achieved by following a recent recommendation of the Maryland Health Care Commission in its recent comprehensive review of CON: "The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission." (MHCC 2001).

CONCLUDING OBSERVATIONS

The Center is not in a position to weigh the various trade-offs identified in this report. Thus, it is not in a position to recommend whether acute care CON be ended entirely or instead "mended" in a variety of possible ways. However, it does seem reasonable to conclude from these findings that retaining the current CON program unchanged probably is undesirable. There are sufficient problems or limitations of the current program that portions either should be scrapped or at least modified. Moreover, if cost containment is no longer the central justification for CON, this may mean that strengthening certain aspects—e.g., monitoring and enforcement of project delivery standards—may merit consideration.

The Center recognizes there are legitimate concerns raised by reliance on markets to hold down spending, including what would happen to cost shifting now used to finance uncompensated care. Michigan cannot and should not ignore these looming threats; however, CON has only a very limited potential to offset forces of this magnitude. In the long run, the Center believes Michigan may be better served by explicitly considering how to address these critical funding shortfalls directly rather than placing an unrealistic expectation on the CON program to overcome the funding reductions for these activities that will stem from increasing competition and federal budget changes. Likewise, it may make little sense to rely on CON to carry out functions such as quality assurance that can be better performed by other more direct or more cost-effective approaches. It was beyond the scope of this report to explore these alternatives and the mere existence of such alternatives is no guarantee they would be more cost-effective than CON. Only further study could determine this for certain.

In short, the evidence provided by this report does not provide unambiguous evidence that acute care CON in Michigan has failed and should be ended; nor does it provide incontestable proof that CON has succeeded in its objectives and unequivocally should be retained. What all sides might be able to agree upon is that the program can and should be improved so that it attains its objectives in the most efficient and equitable fashion.

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